



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program Core Medical Services Waiver

Application Requirements

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Notice with Opportunity for Comment

SUMMARY: Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White Program or RWP), requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS identified and eligible under the statute. The statute also grants the Secretary authority to waive this requirement if there are no waiting lists for the AIDS Drug Assistance Program (ADAP) and core medical services are available to all individuals identified and eligible under Title XXVI in an applicant's service area.

Prior to this policy announcement, grantees seeking a waiver of the 75 percent requirement have been required to submit core medical services waiver requests at the same time as the annual grant application. Recognizing RWP grantees' request for additional flexibility in the timing of waiver applications, the Health Resources and Services Administration (HRSA) is providing grantees additional options for making waiver requests.

HRSA is amending the uniform waiver standards for RWP grantees requesting a core medical services waiver for fiscal year (FY) 2014 and beyond. The amended standards will allow grantees to apply for a waiver (a) at the same time as their annual Part A, B, or C application submission, (b) at any time up to their annual Part A, B, or C application submission, or (c) up to four months after their grant award for that funding year. This **Federal Register** notice seeks to make public the revised policy and provide an opportunity for public comment before its implementation.

DATES: Comments on this final policy must be received by [INSERT DATE 30 DAYS FROM PUBLICATION DATE]. The policy will become effective on [INSERT DATE 120 DAYS FROM PUBLICATION DATE].

ADDRESSES: Written comments should be sent via email to the Division of Policy and Data, HIV/AIDS Bureau, Health Resources and Services Administration at RyanWhiteComments@hrsa.gov by [INSERT DATE 30 DAYS FROM PUBLICATION DATE].

FOR FURTHER INFORMATION CONTACT: Theresa Jumento using the email above or by telephone at (301) 443-5807.

SUPPLEMENTARY INFORMATION: In response to the requests from the grantee community, and in order for grantees to plan appropriately, HRSA is revising the requirement that core medical services waiver requests be submitted with an applicant's grant application for

the upcoming fiscal year. Under this revision, grantees may submit core medical services waiver requests prior to the annual grant application, with the application, or up to four months after the grant award date. HRSA believes that this change will allow grantees to more robustly assess and develop their funding and service delivery proposal. In addition, if the waiver request has already been received and approved, the application can be based on the approved waiver, and therefore include allocation tables based on that approval. Further, HRSA is clarifying that grantees approved for a core medical services waiver are not compelled to implement that waiver should the grantee determine that the actual needs of the jurisdiction are best met by maintaining funding for core medical services.

This revision replaces policy notice #08-02 and more clearly outlines the requirements to request a waiver of the core medical services provision. In response to concerns expressed by grantees, it provides additional clarity with regard to specific documentation expectations for each element of the waiver. It specifies clearly those documentation expectations whether the waiver request is submitted separately or jointly with the annual funding application.

For waiver applicants that do not submit their request with their annual grant application, HRSA is now requiring that these applicants submit a tentative allocation table outlining the percentage of funds that the grantee plans to spend on core medical and support services under the waiver, if approved. This will provide additional information to HRSA on how the grantee anticipates allocating its resources and will help to demonstrate that the request for a waiver is consistent with either the applicant's forthcoming grant application or their proposed budget revision. In addition to the applicant's annual grant application, waiver applicants now must also

demonstrate that the proposed waiver is also consistent with the Comprehensive Plan and Statewide Coordinated Statement of Need.

The revised policy removes the section entitled “Types of Documentation and Evidence.” Instead, the requirements for the waiver are listed and then the policy specifies the documentation necessary to establish compliance. These changes clarify the documentation that grantees must use to meet each core medical services waiver request requirement. By standardizing the documentation for all grantees, HRSA will gain a clearer understanding of the availability of core medical services in the applicant’s jurisdiction. Furthermore, HRSA will be able to make a more informed decision about the appropriateness of waiving the core medical services requirement in a jurisdiction.

In addition, the standardization of the documentation will ensure that HRSA has sufficient information to make an informed decision on each waiver request. Finally, the revised policy imposes a page number limitation on the narrative section of the core medical services waiver request. In addition, applicants will now submit core medical services waiver requests through the Electronic Handbook (EHB) Prior Approval portal when the core medical services waiver application is not being submitted with an annual grant application.

These revisions are intended to clarify the waiver process, and respond to the changing needs of the grantee community, while at the same time ensuring that the waiver process is fair and sufficiently robust so that HRSA undertakes appropriate reviews.

Policy

Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Parts, A, B, and C

POLICY NUMBER 13-xx (Replaces Policy Notice 08-02)

Scope of Policy

Ryan White Parts A, B, C

Summary and Purpose of Policy

The purpose of this policy is to outline the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) requirements for applying for a waiver of the requirement that 75 percent of Ryan White HIV/AIDS program funds be spent on core medical services.

Background

Title XXVI of the Public Health Service Act, Part A section 2604(c), Part B section 2612(b), and Part C section 2651(c) requires that grantees expend not less than 75 percent of their grant funds on core medical services. These sections also grant the Secretary authority to waive this requirement if there are no waiting lists for the AIDS Drug Assistance Program (ADAP) and core medical services are available to all individuals identified and eligible under Title XXVI in an applicant's service area.

Policy

Grantees may submit a waiver request at any time prior to submission of the annual grant application, along with the annual grant application, or up to 4 months after the start of the grant year for which a waiver is being requested. Applications submitted before or after an annual grant application have different requirements than those submitted with an annual grant application. Applicants should choose the method that best meets their needs. The requirements for each process are outlined below.

Requirements to Apply for a Waiver Before or After an Annual Grant Application

This section outlines the requirements to submit a waiver application: (1) in advance of a grantee's annual grant application or (2) after the grant application has been submitted up to 4 months into the grant year for which a waiver is being requested. Waiver requests must be submitted through the EHB *Prior Approval* portal and must identify the grant year for which the waiver is being requested. The waiver request must be signed by the chief elected official or the Project Director, and include the following documentation that will be utilized by HRSA in determining whether to grant the waiver:

1. Letter signed by the Director of the Part B State/Territory Grantee indicating that there is no current or anticipated ADAP services waiting list in the State/Territory.
2. Evidence that all core medical services listed in the statute (Part A section 2604(c)(3), Part B section 2612(b)(3), and Part C section 2651(c)(3)), regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available and accessible

within 30 days for all identified and eligible individuals with HIV/AIDS in the service area, without need to expend at least 75 percent of Ryan White funds on these services.

Acceptable evidence must include all of the following:

- a. HIV/AIDS care and treatment services inventories, including identification of the specific core medical services available, from whom, and through what funding source;
 - b. HIV/AIDS client/patient service utilization data in addition to what has previously been submitted via the Ryan White Services Report (RSR); and
 - c. Letters from Medicaid and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers.
3. Evidence of a public process, which documents that the applicant has sought input from affected communities; including consumers and the Ryan White HIV/AIDS Program-funded core medical services providers, related to the availability of core medical services and the decision to request a waiver. This public process may be the same one that is utilized for obtaining input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, Statewide Coordinated Statement of Need (SCSN), public planning, and/or needs assessment process.

Acceptable evidence must, at a minimum, include:

- a. Letters from both the Planning Council Chair in the Metropolitan area (if grantee serves such area) and the State HIV/AIDS Director describing the public process that occurred in each jurisdiction.
4. A narrative of up to, but no more than, 10 pages that explains each item in a. through d. below:
 - a. Any underlying State or local issues that influenced the grantee's decision to request a waiver.
 - b. How the documentation submitted under item two supports the assertion that such core services are available and accessible to all individuals with HIV/AIDS, identified and eligible under Title XXVI in the service area.
 - c. How the approval of a waiver will positively contribute to the grantee's ability to address service needs for HIV/AIDS non-core services. Specifically address the grantee's ability to perform outreach and linkage of HIV-positive individuals not currently in care.
 - d. How the receipt of the core medical services waiver will allow for implementation consistent with the applicant's proposed percentage allocation of resources, comprehensive plan, and SCSN. Applicants must also document consistency by providing a proposed allocation table.

Waiver Review and Notification Process

HRSA/HAB will review the request and notify grantees of waiver approval or denial within eight weeks of receipt of the request. Core medical services waivers will be effective for the grant award period for which it is approved. Subsequent grant periods will require a new waiver request. Grantees that are approved for a core medical services waiver in advance of their annual grant application are not compelled to utilize the waiver should circumstances change.

Requirements to Apply for a Waiver with the Annual Grant Application

This section provides guidance for grantees who wish to submit a waiver request with their annual grant application. Waiver requests must be submitted as an attachment to the grantee's annual grant application and should **not** be submitted through the EHB *Prior Approval* portal. The waiver request must be signed by the chief elected official or the Project Director, and include the following documentation that will be utilized by HRSA in determining whether to grant the waiver:

1. Letter signed by the Director of the Part B State/Territory Grantee indicating that there is no current or anticipated ADAP services waiting list in the State/Territory.
2. Evidence that all core medical services listed in the statute (Part A section 2604(c)(3), Part B section 2612(b)(3), and Part C section 2651(c)(3)), regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available and accessible within 30 days for all identified and eligible individuals with HIV/AIDS in the service

area, without need to expend at least 75 percent of Ryan White funds on these services.

Acceptable evidence must include all of the following:

- a. HIV/AIDS care and treatment services inventories, including identification of the specific core medical services available, from whom, and through what funding source;
 - b. HIV/AIDS client/patient service utilization data in addition to what has previously been submitted via the Ryan White Services Report (RSR); and
 - c. Letters from Medicaid and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers.
3. Evidence of a public process, which documents that the applicant has sought input from affected communities; including consumers and the Ryan White HIV/AIDS Program-funded core medical services providers, related to the availability of core medical services and the decision to request a waiver. This public process may be the same one that is utilized for obtaining input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, Statewide Coordinated Statement of Need (SCSN), public planning, and/or needs assessment process.

Acceptable evidence must, at a minimum, include:

- a. Letters from both the Planning Council Chair in the Metropolitan area (if grantee serves such area) and the State HIV/AIDS Director describing the public process that occurred in each jurisdiction.
4. A narrative of up to, but no more than, 10 pages that explains each item in a. through d. below:
 - a. Any underlying State or local issues that influenced the grantee's decision to request a waiver.
 - b. How the documentation submitted under item two supports the assertion that such core services are available and accessible to all individuals with HIV/AIDS, identified and eligible under Title XXVI in the service area.
 - c. How the approval of a waiver will positively contribute to the grantee's ability to address service needs for HIV/AIDS non-core services. Specifically address the grantee's ability to perform outreach and linkage of HIV-positive individuals not currently in care.
 - d. How the receipt of the core medical services waiver is consistent with the applicant's grant application, comprehensive plan, and SCSN. Applicants must also document consistency by providing the following:

- i. Proposed allocation table, if not included as part of the grant application

AND

- ii. (PART A) “Description of Priority Setting and Resource Allocation Processes” and “Unmet Need Estimate and Assessment” sections of the current grant application;

OR

- iii. (PART B) “Needs Assessment and Unmet Need” section of the current grant application;

OR

- iv. (PART C) “Description of the Local HIV Service Delivery System” and “Current and Projected Sources of Funding” sections of the current grant application.

Waiver Review and Notification Process

HRSA/HAB will review the request and notify grantees of waiver approval or denial no later than the date of issuance of the Notice of Award (NoA). Core medical services waivers will be effective for the grant award period for which it is approved. Subsequent grant periods will

require a new waiver request. Grantees that are approved for a core medical services waiver in their annual grant application are not compelled to utilize the waiver should circumstances change.

The Paperwork Reduction Act of 1995

This activity has been reviewed and approved by the Office of Management and Budget, under the Paperwork Reduction Act of 1995 (Control number 0915-0307).

Dated: May 17, 2013

Mary K. Wakefield,
Administrator

[FR Doc. 2013-12354 Filed 05/23/2013 at 8:45 am; Publication Date: 05/24/2013]